CONGRESSIONAL BUDGET OFFICE
PAY-AS-YOU-GO ESTIMATE

October 31, 2000

H.R. 4365
Children's Health Act of 2000

As cleared by the Congress on September 27, 2000, and signed by the President on October 17, 2000

SUMMARY

H.R. 4365 (enacted as Public Law 106-310) will allow individuals with certain vaccine-related injuries to file petitions for compensation under the National Vaccine Injury Compensation program. The act also enables qualifying physicians who wish to dispense certain narcotic drugs for detoxification treatment to apply to the Department of Health and Human Services (HHS) for a waiver of the Drug Enforcement Administration's (DEA) registration requirements.

CBO estimates that H.R. 4365 will increase outlays from the National Vaccine Injury Compensation Trust Fund by $7 million over the 2001-2005 period. The act will also increase federal Medicaid spending by $30 million over the same period.

Table 1 summarizes the act's effects on direct spending. For pay-as-you-go purposes, only the effects in the budget year and the subsequent four years are counted.

TABLE 1. SUMMARY OF THE EFFECTS OF H.R. 4365 ON DIRECT SPENDING

	By Fiscal Year, in Millions of Dollars									
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Changes in outlays	2	8	7	10	10	10	5	5	5	5
Changes in receipts	Not applicable									

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated impact of H.R. 4365 on direct spending is detailed in Table 2. The costs of this legislation fall within budget function 550 (health).

TABLE 2. ESTIMATED EFFECTS OF H.R. 4365 ON DIRECT SPENDING

	By Fiscal Year, Outlays in Millions of Dollars				
	2001	2002	2003	2004	2005
CHANGES IN DIRECT SPENDING					
National Vaccine Injury Compensation	2	3	2	a	0
Medicaid	a	5	5	10	10
Total changes	2	8	7	10	10

a. Less than $500,000.

BASIS OF ESTIMATE

National Vaccine Injury Compensation Trust Fund

Subtitle A of title XVII will allow individuals who require hospitalization and surgical intervention for the treatment of vaccine-related injuries to file petitions in the United States Claims Court for compensation under the National Vaccine Injury Compensation Program. This program provides a system of no-fault compensation for certain individuals who have been injured by specific childhood vaccines. Successful claimants under the program receive compensation for unreimbursable medical expenses, earnings losses, and pain and suffering from the National Vaccine Injury Compensation Trust Fund.

Under prior law, petitioners were required to demonstrate that they suffered from a vaccine-related illness, disability, injury, or condition for more than six months after the administration of the vaccine, or died from a vaccine-related injury. This requirement barred individuals with injuries lasting less than six months from filing a petition for compensation.

The act will primarily affect individuals who sustained injuries from the rotavirus vaccine, which was recommended for routine administration to children in early 1999.

(Rotavirus causes severe diarrhea in infants and young children.) Officials at the Centers for Disease Control (CDC) subsequently found a link between the vaccine and a painful bowel obstruction (intussusception) that in some instances required surgical intervention, and the CDC advised against administration of the vaccine in early 2000. According to the Health Resources and Services Administration, which administers the program, there were about 240 injuries related to the rotavirus vaccination during the time it was administered. About one-half of those injuries required hospitalization and surgical intervention. The balance were treated with a barium enema.

CBO expects that petitions for past rotavirus vaccine injuries will be filed over a three-year period as potential claimants learn they are eligible. A small portion of those petitions will likely be found as ineligible. Based on the program's experience with other claims and the relatively straightforward nature of the injury, CBO expects that most awards will be granted within a year of filing. CBO estimates that about 30 awards will be granted in 2001, 45 in 2002, 30 in 2003, and five in 2004.

Awards for rotavirus vaccine injuries will average about $65,000 per claimant, but may vary widely in specific cases, CBO estimates. That amount takes into account the one-time costs of surgery and hospitalization ($10,000 to $15,000), and an additional award for pain and suffering. Average awards under the program for pain and suffering are about $200,000. (Awards for pain and suffering and for deaths are both capped at $250,000.) Because of the short-term nature of the rotavirus vaccine injury, CBO anticipates that awards will be about $50,000.

CBO estimates that this title will increase outlays from the National Vaccine Injury Compensation Trust Fund by $7 million over the 2001-2005 period. Because the law requires that the trust fund pay before Medicaid, the Medicaid program could realize some savings under the act. CBO anticipates that those savings will be less than $250,000 a year.

Medicaid

Title XXXV, the Drug Addiction Treatment Act of 2000, will permit physicians to dispense and prescribe narcotic drugs in schedules III, IV, or V (the drugs rated the lowest risk for abuse) for maintenance and detoxification treatment, under certain conditions, without obtaining a separate DEA registration. Under prior law, physicians wishing to dispense narcotic drugs to treat narcotic dependence first had to apply to HHS, which determined if they were qualified to provide such treatment. Qualified physicians then had to apply to DEA to be registered separately to dispense (not prescribe) such narcotic drugs in treatment. CBO estimates that this title will increase federal Medicaid spending by $30 million over the 2001-2005 period because more Medicaid beneficiaries will receive new schedule III, IV,

or V narcotics over that period than under prior law. Currently, none of those narcotics are approved for outpatient maintenance or detoxification treatment. Methadone, a schedule II narcotic, is the principal narcotic used in treating opiate addiction. The distribution of methadone is regulated so that only certain providers who are registered with the DEA may dispense it, and the daily doses must be provided in clinical settings and combined with counseling and other treatment services.

The Food and Drug Administration is expected to approve a new substance, buprenorphine, for the treatment of opiate addiction in 2001. According to HHS, buprenorphine is likely to be approved as a schedule IV or V narcotic because it has been found to have limited euphorigenic effects and therefore low desirability for illegal sale. Under prior law, HHS planned to issue regulations allowing physicians to prescribe the drug from their offices and to distribute it through commercial pharmacies.

H.R. 4365 will waive the DEA registration requirement that would otherwise apply to physicians who wish to prescribe buprenorphine and would allow physicians to prescribe that drug from their office-based settings. CBO expects that the act will lead to somewhat wider distribution of buprenorphine for two reasons. First, implementation of office-based distribution will probably occur faster than it would have under prior law. Second, the regulations that the Administration would have issued under prior law would probably have been more restrictive than the procedures allowed by the act.

Based on information from the National Institute on Drug Abuse, CBO estimates that ultimately about 100,000 individuals will receive buprenorphine each year if it is distributed through office-based settings. CBO expects that H.R. 4365 will speed up the penetration of buprenorphine by one to two years and will ultimately lead to 10 percent more people receiving the drug. CBO further estimates that the average annual cost of treatment with buprenorphine will be about $4,600 per person in 2001, evenly divided between the cost of the drug itself and the cost of related medical and mental health services. According to a report by the Institute of Medicine, in 1992 about 12 percent of all methadone treatment was paid for by Medicaid. For this estimate, CBO assumes that the same proportion of buprenorphine treatment will be covered by Medicaid, and that 57 percent of those costs will be reimbursed by the federal government. In addition, CBO estimates that one-quarter of the costs of buprenorphine treatment under the act would either have occurred under prior law or will be offset by reduced use of other medical or mental health services.

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